

Sekura et al, Barker and Kirton et al.

Applicants have filed a DECLARATION OF PRIOR INVENTION IN THE UNITED STATES to overcome cited Patent No. 6,560,165 to Baker as provided under 37 C.F.R. § 1.131. The Baker patent has a filing date of March 28, 2000. Applicants' filing date is May 25, 2000. Less than two months after the Baker filing date. Applicants had requested that a patent application be filed before the Baker patent application was filed. All Applicants' work on their invention occurred in the United States.

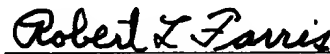
The input of month, date and time of day provides flexibility and the ability to more accurately control the administration of medications. This flexibility is important as medications become more focused on specific ailments and the number of medications taken by a patient increase. Flexibility is also required to manage the interaction between medications.

In view of the Declaration under 37 C.F.R. § 1.131, this application is allowable. Reconsideration and allowance is therefore respectfully requested.

Respectfully submitted,

Indira C. Prabhakar

By her attorney,



Robert L. Farris  
Registration No. 25,112  
5291 Colony Drive North  
Saginaw, Michigan 48603  
989-799-5300



Practitioner's Docket No. 5205.P3005.001

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: **INDIRA C. PRABHAKAR**

Application No.: **09 / 578,277**

Group No.: **2644**

Filed: **MAY 25, 2000**

Examiner: **BRIAN T. PENDLETON**

For: **MEDICINE ADMINISTRATION METHOD**

**Commissioner for Patents**

**Washington, D.C. 20231**

**DECLARATION OF PRIOR INVENTION IN THE UNITED STATES  
OR IN A NAFTA OR WTO MEMBER COUNTRY  
TO OVERCOME CITED PATENT OR PUBLICATION (37 C.F.R. § 1.131)**

NOTE: 37 C.F.R. § 1.131 Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. Prior invention may not be established under this section if either:

(1) The rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 1.601(n); or

(2) The rejection is based upon a statutory bar.

**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is mandatory;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to the Commissioner for Patents, Washington, D.C. 20231

**37 C.F.R. § 1.8(a)**

**37 C.F.R. § 1.10 \***

☐ with sufficient postage as first class mail.

☒ as "Express Mail Post Office to Addressee"

Mailing Label No. EV336241908 US (mandatory)

**TRANSMISSION**

☐ facsimile transmitted to the Patent and Trademark Office, (703)

Kirsten L. Thornton  
Signature

Date: 12/20/04

**KIRSTEN L. THORNTON**

(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome  
Cited Patent or Publication—37 C.F.R. § 1.131 [9-32]—page 1 of 5)

## PURPOSE OF DECLARATION

1. This declaration is to establish completion of the invention of this application in
- ☒ the United States
  - ☐ the NAFTA country \_\_\_\_\_ (name of country)
  - ☐ the WIPO country \_\_\_\_\_ (name of country)

at a date prior to MARCH 28, 2000, that is the effective date of the prior art

- ☐ publication \_\_\_\_\_
- ☒ patent 6,560,165 TO BARKER
- ☐ patent publication \_\_\_\_\_
- ☐ other \_\_\_\_\_

that was cited by the

- ☒ examiner.
- ☐ applicant.

NOTE: 37 C.F.R. § 1.131 is not applicable to a rejection based on a U.S. patent that CLAIMS the rejected invention.

2. The person making this declaration is (are):
- ☒ the inventor(s).
  - ☐ only some of the joint inventor(s)  
(and a suitable excuse is attached for failure of the omitted joint inventor(s) to sign)
  - ☐ the party in interest  
(and a suitable explanation as why it is not possible to produce the declaration of the inventor(s) is attached)

## FACTS AND DOCUMENTARY EVIDENCE

NOTE: "The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained." 37 C.F.R. § 1.131(b).

3. To establish the date of completion of the invention of this application, the following attached documents and/or models are submitted as evidence:

(check all applicable items below)

- ☐ sketches
- ☒ blueprints
- ☐ photographs
- ☐ reproduction(s) of notebook entries
- ☐ model
- ☐ supporting statement(s) by witness(es) (where verbal disclosures are the evidence relied upon)
- ☐ interference testimony
- ☒ disclosure documents

(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome Cited Patent or Publication—37 C.F.R. § 1.131 [9-32]—page 2 of 5)

NOTE: While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder* 1897 C.D. 724, 81 O.G. 1417." See also M.P.E.P. § 715.07 and § 2138.04, 7th ed.

4. From these documents and/or models, it can be seen that the invention in this application was made

☐ on \_\_\_\_\_.

☒ at least by the date of MARCH 12, 2000 which is a date earlier than the effective date of the reference.

NOTE: "If the dates of the exhibits have been removed or blocked off, the matter of dates can be taken care of in the body of the oath or declaration." M.P.E.P. § 715.07, 8th ed.

NOTE: "[T]he dates in the oath or declaration may be the actual dates, or, if the applicant or patent owner does not desire to disclose his or her actual dates, he or she may merely allege that the acts referred to occurred prior to a specified date. However, the actual dates of acts relied on to establish diligence must be provided." M.P.E.P. § 715.07, 8th ed.

### DILIGENCE

NOTE: "Where there has not been reduction to practice prior to the date of the reference, the applicant or patent owner must also show diligence in the completion of his or her invention from a time just prior to the date of the reference continuously up to the date of the actual reduction to practice or up to the date of filing his or her application (filing constitutes a **constructive** reduction to practice, § 1.131)." M.P.E.P. § 715.07, 8th ed..

NOTE: "A conception of an invention, though evidenced by disclosure, drawings, and even a model, is not a complete invention under the patent laws, and confers no rights on an inventor, and has no effect on a subsequently granted patent to another, **UNLESS HE OR SHE FOLLOWS IT WITH REASONABLE DILIGENCE BY SOME OTHER ACT**, such as an actual reduction to practice or filing an application for a patent. *Automatic Weighing Mach. Co. v. Pneumatic Scale Corp., Limited* 1909 C.D. 498, 139 O.G. 991, M.P.E.P. § 715.07, 8th ed.

"Conception in the mental part of the inventive act, but it must be capable of proof, as by drawings, complete disclosure to another person, etc. In *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417, it was established that conception is more than a mere vague idea of how to solve a problem; the means themselves and their interaction must be comprehended also." M.P.E.P. § 715.07, 8th ed.

NOTE: "[O]nly diligence before reduction to practice is a material consideration. The 'lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon' is not relevant to an affidavit or declaration under 37 CFR 1.131. See *Ex parte Merz*, 75 USPQ 296 (Bd. App. 1947)." MPEP § 715.07(a), 8th ed.

5. Attached is a statement establishing the diligence of the applicants, from the time of their conception, to a time just prior to the date of the reference, up to the:

☐ actual reduction to practice.

☒ filing of this application.

(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome Cited Patent or Publication—37 C.F.R. § 1.131 [9-32]—page 3 of 5)

## TIME OF PRESENTATION OF THE DECLARATION

(complete (a), (b) or (c))

- (a) ☐ This declaration is submitted prior to final rejection.
- (b) ☒ This declaration is submitted with the first response after final rejection, and is for the purpose of overcoming a new ground of rejection or requirement made in the final rejection.
- (c) ☐ This declaration is submitted after final rejection. A showing under 37 C.F.R. § 1.116(b) is submitted herewith.

## DECLARATION

6. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

## SIGNATURE(S)

7. (complete A or B below)

A. Inventor(s)

Full name of sole or first inventor INDIRA C. PABHAKER

Inventor's signature *Indira Prabaker*

Date \_\_\_\_\_ Country of Citizenship USA

Residence SAGINAW, MICHIGAN

Post Office Address 3745 DELVAN DRIVE  
SAGINAW, MICHIGAN 48603-1706

Full name of second joint inventor, if any BANGALORE PRABHAKER

Inventor's signature *Prabhaker*

Date \_\_\_\_\_ Country of Citizenship INDIA

Residence SAGINAW, MICHIGAN

Post Office Address 3745 DELVAN DRIVE

(use added page for signature by additional inventors)

Number of pages added: \_\_\_\_\_

(Declaration of Prior Invention in the United States or in a NAFTA or WTO Member Country to Overcome Cited Patent or Publication—37 C.F.R. § 1.131 [9-32]—page 4 of 5)


## STATEMENT

A disclosure document was written by Indira C. Prabahakar, M.D. and signed C. Indira, M.D., her professional name, on the second day of August, 1999.

On September 23, 1999, Mr. John Leonard, an employee of Saginaw Valley State University Engineering Department, signed a confidential disclosure agreement. Mr. Leonard was hired to assist with the construction of prototypes, prototype testing, development of manufacturing processes, development of testing procedures, and development of a quality control procedure. At the time of signing the confidential disclosure agreement, the information in the August 2, 1999 document was disclosed to Mr. Leonard. Over the next five months, additional information was disclosed to Mr. Leonard by Indira C. Prabhakar and Bangalore Prabhakar. On March 12, 2000, Mr. John Leonard sent a schematic diagram of a prototype and a list of parts, together with prices, for the parts needed to build prototype. The parts were ordered soon, on or after the March 12<sup>th</sup> date. The order was made by telephone.

Preparation of a patent application was started on or about March 14, 2000. Patent Drawings were ordered. The application was drafted, reviewed by Indira C. Prabhakar and Bangalore Prabhakar, revised and filed May 25, 2000.

  
INDIRA C. PRABHAKAR

  
BANGALORE PRABHAKAR

C. INDIRA, M.D.  
Diplomate, The American Institute of Pulmonary Medicine  
Diplomate, The American Institute of Internal Medicine



## PILL-GUIDE

Sub: Patent for PILL-GUIDE

Purpose: To facilitate timely intake of medications by patients

Pill-Guide is a user friendly, portable, digital voice recorder that can be programmed by the user or a pharmacist if needed with instructions for taking medications at prescribed intervals. It is operated by a set of batteries or can be plugged to the wall electric outlet.

The instructions will include identification and indication of each pill to watch for, dosages, schedule times. At prescribed timings the patient will hear audio signals which will serve as a reminder for the patient to take the medication. The instructions include reminders for refill. Also, patient will be reminded to contact the physician for additional refills. All these result in reduction of cost of medical care.

Advantages: Patients can be assured of correct dosages and timeliness.  
Unintentional over drug usage will be eliminated.

A handwritten signature in black ink, appearing to read "C. Indira".

C. INDIRA, M.D.

Subscribed to and sworn before me the 2... Day of AUGUST... 1999

A handwritten signature in black ink, appearing to read "Jennifer L. Marcum".

Jennifer L. Marcum  
Notary Public Saginaw County, Mich.  
My Commission Expires 06-02-2002

4370 Fashion Square Blvd., Saginaw, MI 48603  
Tel. 517 799-5441 Fax. 517 799-3590



giridhar.nosalli@aais.bdi.gte.com

## PILL-GUIDE

Pill-Guide is a user friendly, portable, digital voice recorder that can be programmed by the user or a pharmacist if needed with instructions for taking medications at prescribed intervals. It is operated by a set of batteries or can be plugged to the wall electric outlet.

The instructions will include identification and indication of each pill to watch for, dosages, schedule times. At prescribed timings the patient will hear audio signals which will serve as a reminder for the patient to take the medication. The instructions include reminders for refill. Also, patient will be reminded to contact the physician for additional refills. All these result in reduction of cost of medical care.

**Advantages:** Patients can be assured of correct dosages and timeliness. Unintentional over drug usage will be eliminated.

Date: September 23, 1999

This is a confidentiality agreement between C. INDIRA, M.D., JOHN LEONARD as under:

No information in part or full will be disclosed to anybody else without the written permission of C. Indira. Also no attempt will be made to manufacture, market or assist in manufacturing or marketing any product using this information without the written consent of C. Indira. This product with its name has been applied for a Patent.

Sd. C. INDIRA, M.D

Sd. JOHN LEONARD

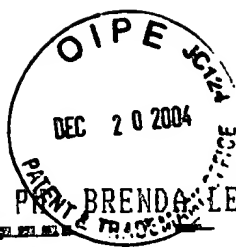
Date: 9-23-99

T. # 835 8120

790 5620

LEONARD SVSU - EDU





MAR-12-2000 10:14 PM BRENDLEONARD

517 835 8120

P. 01

DATE: March 12, 2000  
TO: Ben Prabhakar  
FROM: John Leonard  
RE: "Pill Guide" schematics & parts list

Ben,

On the following pages are:

- a schematic diagram of the prototype;
- a list of parts needed to build 5 working prototype units for testing;
- a list of components with high volume prices.

The last item without a price is a crystal for the real-time clock. I have to call "Arrow / Bell" in Plymouth, MI to get pricing and availability. The other vendor (JDR Microdevices) doesn't publish their volume prices but will e-mail them to me. I'll FAX the information to you as soon as I receive it.

John



# **PARTS LIST FOR BUILDING FIVE WORKING "PILL GUIDE" PROTOTYPE UNITS:**

**Digi-Key Corp.**  
**701 Brooks Ave. South**  
**Thief River Falls, MN 56701-0677**  
**phone: 1-800-344-4539**

part no.	item	quantity	price ea.	total
153-1023-ND	display	5 ea.	\$ 5.70	\$28.50
PIC16C62B/JW-ND	CPU	5 ea.	9.57	47.85
LM386-3-ND	amp I.C.	5 ea.	.91	4.55
ISD4003-04-MP-ND	voice I.C.	5 ea.	10.75	53.75
EG1426-ND	switch	28 ea.	1.31	36.68
EG1098-ND	switch cap	5 ea.	.33	1.65
EG1091-ND	switch cap	5 ea.	.33	1.65
EG1092-ND	switch cap	5 ea.	.33	1.65
EG1095-ND	switch cap	5 ea.	.33	1.65
P9961-ND	microphone	1 ea.	3.01	3.01
P9897-ND	microphone	1 ea.	3.11	3.11
P9959-ND	microphone	1 ea.	2.24	2.24
P9610-ND	speaker	1 ea.	3.76	3.76
P10175-ND	speaker	1 ea.	5.38	5.38
X902-ND	resonator	5 ea.	.68	3.40
P2055-ND	cap, .22uf	15 ea.	.202	3.03
P2053-ND	cap, .1uf	20 ea.	.216	4.32
P4020-ND	cap, 47pf	10 ea.	.10	1.00
P6260-ND	cap, 1uf	10 ea.	.20	2.00
P6228-ND	cap, 220uf	5 ea.	.32	1.60
P4307A-ND	cap, .047uf	10 ea.	.144	1.44
P6247-ND	cap, 4.7uf	5 ea.	.19	.95
10.0KXBK-ND	resistor, 10k	50 ea.	5 / .54	5.40
4.75KXBK-ND	resistor, 4.7k	5 ea.	5 / .54	.54
2.00KXBK-ND	resistor, 2.0k	5 ea.	5 / .54	.54
274KXBK-ND	resistor, 274	5 ea.	5 / .54	.54
SR27SA-ND	enclosure	5 ea.	10.21	51.05

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**Total: \$ 271.24**

**PARTS FOR BUILDING FIVE WORKING "PILL GUIDE" PROTOTYPE UNITS (con't.):**

**JDR Microdevices**  
1850 South 10th St.  
San Jose, CA 95112-4108  
phone: 1-800-538-5000

part no.	item	quantity	price	total:
DS1302	real time clock	5 ea.	\$ 4.49	\$22.45
CD4543	display driver IC	16 ea.	.69	11.04
LED154	red LED	5 ea.	.39	1.95
				<hr/>
				\$35.44

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**Radio Shack**

	blank perf (circuit) board	5 ea.	3.99	19.95
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**Arrow / Bell**  
44720 Helm St.  
Plymouth, MI 48170-0850  
phone: 734-455-0850

part no.	item	quantity	price	total:
C-001R-32.768K-E	crystal	5 ea.	* waiting for prices *	